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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Sterne Kessler Goldstein & Fox PLLC
Attorneys At Law
Suite 600
1100 New York Avenue N W
Washington, DC 20005-3934

EXAMINER
COE, SUSAN D

ART UNIT	PAPER NUMBER
1651	8

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/693,949	Applicant(s) PRICE ET AL.	
	Examin r Susan Coe	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 27-38* is/are pending in the application.

4a) Of the above claim(s) *14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18-21 and 26-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed September 17, 2001 has been received and entered.

2. Claims 29-38 have been added.

3. Claims 22-25 have been cancelled.

4. Claims 1-21 and 26-38 are currently pending.

Election/Restrictions

5. Applicant's election without traverse of Group I, claims 1-13, 18-21, and 26-38, lipoic acid for species A, myristate for species B, stigmastanol for species C, mammalian cells for species D, and potato for species E in Paper No. 7, dated September 17, 2001 is acknowledged.

6. Claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

7. Claims 1-13, 18-21, and 26-38 are examined on the merits.

Priority

8. Applicant's claim for domestic priority is granted. However, applicant does not state if the parent application, 09/302,953, is a continuation, divisional, etc. of its parent applications. Clarification is requested.

In addition, the continuing data paragraph in the specification is in improper format. The paragraph should read: --

This application is a continuation of US Patent Application No. 09/302,953, filed April 30, 1999, now abandoned, which claims priority to US Patent Application No. 09/070,807, filed May 1, 1998, now abandoned, and US Patent Application No. 08/949,142, filed October 10, 1997, now US Pat. No. 6,103,529, which claims priority to US Provisional Patent Application No. 60/028,197, filed October 10, 1996. --

In addition, this paragraph needs to indicate how Application No. 09/302,953 is related to its parent cases. Specifically, that it is continuation, CIP, divisional, etc. of the applications to which priority is claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 32, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 30 and 32 are indefinite because they state that "the lipid or fatty acid is selected from the combination comprising." It is unclear if the lipid or fatty acid is intended to be only one of the members of the Markush group or a combination of two or more of the members.

10. Claims 36-38 are indefinite because they do not properly depend from claim 1. Claim 1 does not state that the culture medium contains plant derived lipids or fatty acids, and claims 36-38 are drawn to this ingredient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-13, 18-21, and 26-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,103,529. Although the conflicting claims are not identical, they are not patentably distinct from each other because US '529 teaches a cell culture medium containing peptides, fatty acids, and lipids derived from plant sources which is the same culture medium that the present claims are drawn to. However, US '529 claims that the culture medium must be completely devoid of animal proteins which is not a limitation in the current claims. However, while the current claims encompass media that contain animal proteins, they are not a requirement. Therefore, the scope of the current claims overlaps with the claims of US '529.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 2, 7, 10, 13, 20, 21, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Iscove et al. (Journal of Experimental Medicine (1978) vol. 147, pp. 923-933).

The claims are drawn to an animal cell culture medium that contains a plant derived lipid or fatty acid.

Iscove teaches a culture medium for B lymphocytes that contains soybean lipids. The soybean lipid mixture contains sterols (see page 927, second paragraph). The lipids are mixed into an Eagle's animal cell culture medium (see last paragraph of page 923).

13. Claims 1, 6, 12, 18, 19, 26, 27, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Keay (Biotechnology and Bioengineering (1975), vol. 17, pp. 745-764).

The claims are drawn to an animal cell culture medium that contains a plant derived peptide.

Keay teaches that soy peptone can be used to culture animal cells (see page 750, Table II).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 2, 5, 7-9, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iscove et al. in view of Gibco BRL Life Technologies, Gaithersburg, MD, 1993-1994 Catalogue and Reference Guide pp. 1-105 through 1-107, 1-115 through 1-116, 1-123, 4-49, 4-50, 4-61, and 4-63.

As stated above, Iscove teaches a culture medium that contains soybean lipids. However, Iscove does not teach adding lipoic acid or myristate to the culture medium. The Gibco catalog shows that both lipoic acid (see page 1-105) and myristate(see page 4-63) are ingredients that can be added to a culture medium. Based on this teaching, a person of ordinary skill in the art would reasonably assume that these ingredients could beneficially be added to the culture medium taught by Iscove. Therefore, an artisan of ordinary skill would have been motivated to add lipoic acid and myristate to the culture medium of Iscove.

15. Claims 2, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iscove et al. in view of CAPLUS abstract of Japanese Pat. No. 34002673 (April 1959).

As stated above, Iscove teaches a culture medium that contains soybean lipids. The lipid mixture contains sterols. However, the reference does not specifically teach that the sterol mixture contains stigmastanol.

JP '673 teaches that soybean contains the sterol stigmastanol. Based on this teaching by JP '673, a person of ordinary skill in the art would reasonably expect that the sterol mixture used in Iscove contained stigmastanol. Based on this expectation, an artisan of ordinary skill would have a reasonable expectation that using the soybean sterol stigmastanol in the culture medium taught by Iscove would be successful. Thus, an artisan of ordinary skill would have been motivated to use stigmastanol in the culture medium taught by Iscove.

16. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keay in view of Gibco Catalogue.

As stated above, Keay teaches using soy peptone to culture animal cells. The Gibco Catalogue teaches that lipoic acid (see page 1-105) can be added to a culture medium. Based on this teaching, a person of ordinary skill in the art would reasonably assume that these ingredient could beneficially be added to the culture medium taught by Keay. Therefore, an artisan of ordinary skill would have been motivated to add lipoic to the culture medium of Keay.

17. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iscove et al. and Keay.

The claims are drawn to an animal culture media containing both plant peptides and lipids.

As stated above, Iscove teaches using plant lipids in animal culture media. Keay teaches using plant peptides in animal culture media. These references show that it was well known in the art at the time of the invention to use plant peptides and lipids animal culture media. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition

which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by Iscove and Keay that these two substances are used in animal culture media, an artisan of ordinary skill would have a reasonable expectation that a combination of the six substances would also be useful in creating an animal culture media. Therefore, the artisan would have been motivated to combine plant lipids and plant peptides into a single culture media. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

18. Claims 1-7, 12, 13, 18-21, 26-28, and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,122,469.

US '469 teaches a culture media for animal cells that can contain peptone. It states that the peptone can be obtained from plant material (see column 7, lines 59-64). The culture medium can also contain lipids extracted from plant sources (see column 8, lines 58-63). In addition, the culture medium can contain lipoic acid (see column 6, line 4). This reference shows that plant peptides, lipids, and lipoic acid can all be used in animal cell culture media; however, the reference does not explicitly teach a single embodiment that uses all of these ingredients together. However, since all of the ingredients can be used for the same purpose, an artisan of ordinary skill in the art would reasonably expect that a combination of the ingredients would form a media capable of culturing animal cells. Therefore, a person of ordinary skill in

the art would have been motivated to create a culture media containing plant lipids, plant peptides, and lipoic acid.

US '469 also does not specifically teach that potato can be used as a source of the lipids and peptides. However, it is known in the art that potatoes contain these substances; therefore, an artisan of ordinary skill would reasonably expect that potatoes could be used as a source of the lipids and peptides. Thus, a person of ordinary skill in the art would have been motivated to use potato as the plant source of the ingredients of the culture medium.

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
November 29, 2001

FRANCISCO PRATS
PRIMARY EXAMINER